

# Declaration For U.S. Patent Application

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

(Insert Title) Compounds with improved cartilage-inducing and/or bone-inducing activity

the specification of which

- (Check one of blocks 1, 2 or 3. See note A on back of this page)
1. ☐ is attached hereto.
  2. ☒ was filed on 19 November 1997 as International PCT Application Serial No. PCT/EP97/06463 and was amended on \_\_\_\_\_ (if applicable)
  3. ☐ was filed on \_\_\_\_\_ as U.S. Application Serial No. \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application for which priority is claimed:

	<u>196 47 853.7</u>	<u>Germany</u>	<u>19/Nov/1996</u>	Priority Claimed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
(List prior foreign applications. See note B on back of this page)	(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
	(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
	(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
	(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No

(See Note C on back of this page)

☐ See attached list for additional prior foreign applications

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT International filing date of this application:

(List prior U.S. Applications or PCT International applications designating the U.S.)

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

12) And I hereby appoint as principal attorneys David T. Nikaido, Reg. No. 22,663; Charles M. Marmelstein, Reg. No. 25,895; George E. Oram, Jr., Reg. No. 27,931; Robert B. Murray, Reg. No. 22,980; Martin S. Postman, Reg. No. 18,570; E. Marcie Emas, Reg. No. 32,131; Michael G. Gilman, Reg. No. 19,114; Douglas H. Goldhush, Reg. No. 33,125; Kevin C. Brown, Reg. No. 32,402; Monica Chin Kitts, Reg. No. 36,105; Sharon N. Klesner, Reg. No. 36,335; and John R. Fuisz, Reg. No. 37,327.

Please direct all communications to the following address: NIKAI, MARMELSTEIN, MURRAY & ORAM  
Metropolitan Square  
655 Fifteenth Street, N.W., Suite 330 - G Street Lobby  
Washington, D.C. 20005-5701  
(202) 638-5000 Fax: (202) 638-4810

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(See Note D on back of this page)

Full name of sole or first inventor Michael PAULISTA  
 Inventor's signature Michael Paulista 11.7.99  
 Residence D-69181 Leimen, Federal Rep. of Germany Date  
 Citizenship German DEX  
 Post Office Address Wingertstraße 10, D-69181 Leimen, Germany

## NOTES

- A. 1. For declaration to be filed with original U.S. (Non-PCT) Application Papers, check box 1.
2. For declaration to be filed in U.S. National Phase of PCT Application (either with original national phase entry papers or subsequent to expiration of 20 or 30 month term), check box 2, and complete information.
3. For declaration to be filed after original U.S. (Non-PCT) Application filing date, check box 3, and complete information.
- B. Please list all non-convention foreign applications relating to the invention (and check block "no"), as well as all convention (priority) applications.
- C. If more than 4 prior foreign applications, please check this box and attach a sheet listing the remaining prior foreign applications.
- D. For the Inventor's "Residence", only the city and state is necessary, however the "Post Office Address" must be an address acceptable by a Post Office for delivery of mail.

Serial or Patent No.:

Docket No.:

Filed or Issued:

To:

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27(c) - SMALL BUSINESS CONCERN)

I hereby declare that I am

- ( ) the owner of the small business concern identified below:  
(X) an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN GerontoCare GmbH Biomaterials & Medical Devices

ADDRESS OF CONCERN Rossberggring 107, D-64354 Reinheim/Odw., Germany

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduces 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, on concern controls or has the power to control the other, or a third party or parties control or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled Compounds with improved cartilage-inducing and/or bone-inducing activity by Inventor(s) Michael Paulista, Jens Pohl, Joachim Pabst, Helmut Heide described in

( ) the specification filed herewith

( ) application serial no. \_\_\_\_\_ filed \_\_\_\_\_

( ) patent no. \_\_\_\_\_, issued \_\_\_\_\_

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or L, concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

( ) INDIVIDUAL ( ) SMALL BUSINESS CONCERN ( ) NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING X Dr. Joachim Pabst

TITLE OF PERSON OTHER THAN OWNER X Marketing & Sales Manager Germany

ADDRESS OF PERSON SIGNING X Rossberggring 107, D-64354 Reinheim,

SIGNATURE X Joachim Pabst

DATE X 13.05.1999

Serial or Patent No.: \_\_\_\_\_ Docket No.: \_\_\_\_\_

Filed or Issued: \_\_\_\_\_

To: \_\_\_\_\_

VERIFIED STATEMENT (DECLARATION ) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27(c) - SMALL BUSINESS CONCERN

I hereby declare that I am

- ( ) the owner of the small business concern identified below:  
( X ) an official of the small business concern empowered to act on behalf  
of the concern identified below:

NAME OF CONCERN Biopharm Gesellschaft zur biotechnologischen Entwicklung von Pharmaka mbH

ADDRESS OF CONCERN Czernyring 22, D-69115 Heidelberg, Germany

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

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- ( X ) the specification filed herewith  
( ) application serial no. \_\_\_\_\_ filed \_\_\_\_\_  
( ) patent no. \_\_\_\_\_, issued \_\_\_\_\_

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING X Michael Paulista

TITLE OF PERSON OTHER THAN OWNER X

ADDRESS OF PERSON SIGNING X Biopharm GmbH, Czernyring 22, 69115 HEIDELBERG

SIGNATURE V M. Paulista DATE V 5.3.99

Full name of second joint inventor, if any Jens POHL  
Inventor's signature X [Signature] March 5, 1999  
Residence D-76707 Hambrücken, Federal Republic of Germany  
Citizenship German DEX  
Post Office Address Bastwaldstraße 25, 76707 Hambrücken, Germany

Full name of third joint inventor, if any 3-00 Joachim PABST  
Inventor's signature X [Signature] April 6, 1999  
Residence D-64354 Reinheim, Federal Republic of Germany  
Citizenship German DEX  
Post Office Address Rossberggring 107, D-64354 Reinheim, Germany

Full name of fourth joint inventor, if any 4-00 Helmut HEIDE  
Inventor's signature X [Signature] April 6, 1999  
Residence D-65779 Kelkheim, Federal Republic of Germany  
Citizenship German DEX  
Post Office Address Am Hohenstein 14, D-65779 Kelkheim, Germany

Full name of fifth joint inventor, if any \_\_\_\_\_  
Inventor's signature \_\_\_\_\_  
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Citizenship \_\_\_\_\_  
Post Office Address \_\_\_\_\_

Full name of sixth joint inventor, if any \_\_\_\_\_  
Inventor's signature \_\_\_\_\_  
Residence \_\_\_\_\_  
Citizenship \_\_\_\_\_  
Post Office Address \_\_\_\_\_

Full name of seventh joint inventor, if any \_\_\_\_\_  
Inventor's signature \_\_\_\_\_  
Residence \_\_\_\_\_  
Citizenship \_\_\_\_\_  
Post Office Address \_\_\_\_\_

Full name of eighth joint inventor, if any \_\_\_\_\_  
Inventor's signature \_\_\_\_\_  
Residence \_\_\_\_\_  
Citizenship \_\_\_\_\_  
Post Office Address \_\_\_\_\_